UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/525,998	03/15/2000	Rudolph Hauptmann	98,385-E	1361

20306 7590 06/17/2002

MCDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
SUITE 3200
CHICAGO, IL 60606

EXAMINER
O'HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/17/2002

/E

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/525,998	HAUPTMANN ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-21 and 24-148* is/are pending in the application.

4a) Of the above claim(s) *19-21 and 24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-148* is/are rejected.

7)☒ Claim(s) *136,137,140-143 and 148* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. Claims 19-21 and 24-148 are pending in the instant application.

Corrected Filing Receipt

2. The request for correction of filing receipt filed June 16, 2000 has been entered.

Election/Restrictions

3. Applicant's election with traverse of nucleic acid molecules comprising the nucleotide sequences set forth in SEQ ID NO: 1 and 3, Group A, in Paper No. 15 is acknowledged. The traversal is on the ground(s) that there would be no undue hardship on the Office in performing a search with respect to the other nucleic acid molecules because of the substantial degree of homology between the encoded amino acid sequences set forth in SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14, 16, 18 and 20 and present the alignment in Exhibit A. This has been found persuasive and therefore all of the nucleic acid sequences of Groups A-I will be examined.

Claims 19-21 and 24-26 are withdrawn as being drawn to a non-elected invention.

Claims 27-148 are currently under examination.

Information Disclosure Statement

4. The information disclosure statement filed October 24, 2000 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Most of the references were present in the IDS and were considered, but the references that are lined through were not present and have not been considered.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-148 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-63 of U.S. Patent No. 6,294,352. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to nucleic acids encoding polypeptides that are truncations/deletions of the full length TNF receptor polypeptide shown in SEQ ID NO: 2 that retain TNF binding activity (Figure 9 in both application and patent). The truncations/deletions are obvious because the skilled artisan would want to determine and use polypeptides that retain TNF binding activity but may be smaller than the full length polypeptide or other larger truncations.

Claim Objections

6. Claims 132, 136, 137, 140-143 and 148 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 41-48, 71-76, 78, 83-86, 89-91, 96, 97 and 104-148 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7.1 Claims 41-48 and dependent claims 71-74, 76, 78, 83-86, 89-91, 96, 97, 104-148 are indefinite because the "at least one" language of the claims does not place an upper limit on the extent of the changes to be made. For example, as written, it may be possible to make conservative amino acid substitutions at every amino acid residue and still bind TNF, but the protein would be completely different from those of the recited SEQ ID NOS. Therefore, the claims fail to adequately point out that which Applicant sees as the invention.

7.2 Claim 75 is indefinite because it encompasses a nucleic acid molecule which hybridizes under "**moderately or highly stringent**" conditions, and there are no hybridization conditions defined in the specification. The term "**moderately or highly stringent**" is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

7.3 Claim 132 is indefinite because it is an incomplete method claim. There is no preamble describing the purpose of the method, and no method steps recited to achieve amplification. Additionally, it is not clear what nucleic acid is to be amplified, since the host cell also comprises endogenous nucleic acid molecules as well as the recombinantly introduced nucleic acid molecule.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 41-47 and 75 (and dependent claims) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes a polypeptide sequence consisting of SEQ ID NO: 2 as well as the amino and carboxy terminal truncation/deletions variants of SEQ ID NOS: 4, 6, 8, 10, 12, 14, 16, 18 and 20, all of which comprise the same core sequence of amino acids 41-201 of SEQ ID NO: 2 (which is SEQ ID NO: 4) and all of which are shown to have the activity of binding TNF. However, the claims as written include nucleic acid molecules encoding polypeptides comprising fragments and homologues, encompass polypeptides that vary substantially in length and also in amino acid composition. Due to unlimited changes, no conservation of structure is required. The instant disclosure of a core polypeptide, that of SEQ ID NO: 4 with the instantly disclosed specific activity, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614,

1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, only polypeptides comprising the same core sequence SEQ ID NO: 4. Given the unpredictability of changing amino acids on the activities of proteins, and the fact that the specification fails to provide objective evidence that the additional sequences are indeed species of the claimed genus it cannot be established that a representative number of species have been disclosed to support the genus claim.

Conclusion

9.1 No claim is allowed.

9.2 Claims 27-148 are rejected.

9.3 Claims 136, 137, 140-143 and 148 are objected to.

The art considered pertinent to the present application is Wallach et al., PN 5,811,261, (cited by Applicant) which discloses a polypeptide which is 100% identical to the polypeptide of SEQ ID NO: 2 of the present application. This is not considered prior art since the priority date is later than the priority date of the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

LORRAINE SPECTOR
PRIMARY EXAMINER